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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 133. HOSPITAL LICENSING
SUBCHAPTER J. HOSPITAL LEVEL OF CARE DESIGNATIONS FOR NEONATAL CARE

25 TAC §§133.181 - 133.191

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), adopts amendments to §133.181, concerning Purpose; §133.182, concerning Definitions; §133.183, concerning General Requirements; §133.184, concerning the Designation Process; §133.185, concerning Program Requirements; §133.186, concerning Neonatal Designation Level I; §133.187, concerning Neonatal Designation Level II; §133.188, concerning Neonatal Designation Level III; §133.189, concerning Neonatal Designation Level IV; §133.190, concerning the Survey Team; and new §133.191, concerning the Perinatal Care Regions (PCRs). The amendments to §§133.182 - 133.190 are adopted with changes to the proposed text as published in the January 13, 2023, issue of the *Texas Register* (48 TexReg 83) and the sections will be republished. The amendment to §133.181 and new §133.191 are adopted without changes and will not be republished.

BACKGROUND AND JUSTIFICATION

The adoption updates the content and processes with the advances and practices since these rules were adopted in 2016. Senate Bill (S.B.) 749, 86th Legislature, Regular Session, 2019, amended the Texas Health and Safety Code, Chapter 241. S.B. 749 requires language specific to waiver agreements, a three-person appeal panel for designation reviews, and language specific to telemedicine and telehealth be integrated into the neonatal rules.

In addition, the Perinatal Advisory Council (PAC) provided DSHS with rule language recommendations designed to clarify specific subsections of the rules. The recommendations include the use of prearranged consultative agreements using telemedicine technology, and consideration of a waiver agreement for facilities that cannot meet a specific designation requirement. The recommendations further define the process for the three-person appeal panel, clarify that pediatric echocardiography with pediatric cardiology interpretation and consultation to be completed in a time period consistent with standards of professional practice, and include national accredited organizations providing resuscitation courses.

The PAC formed a workgroup to collaborate with DSHS staff to review the public comments received and determine the most appropriate language to ensure the health and safety of neonatal patients and prevent any undue burden on the facilities providing neonatal care.

COMMENTS

During the 31-day comment period, DSHS received comments from 35 commenters, including the American Academy of Pediatrics (AAP); Baylor Scott & White Health (BSWH); Children's Hospital Association of Texas (CHAT); Children's Hospital of San Antonio (CHoSA); CHRISTUS Health; CHRISTUS Southeast Texas Health System; CHRISTUS St. Michael Health System; East Texas Gulf Coast Regional Advisory Council; Harris Health System; HCA Houston Healthcare Southeast; Medical City Healthcare; Methodist Children's Hospital; Methodist Hospital Stone Oak; Metropolitan Methodist Hospital; Parkland Health; Teaching Hospitals of Texas (THOT); Tenet Healthcare; Texas Association of Nurse Anesthetists (TxANA); Texas EMS, Trauma and Acute Care Foundation (TETAF)/Texas Perinatal Services; Texas Health Presbyterian Hospital Dallas; Texas Hospital Association (THA); Texas Medical Association (TMA) representing three additional physician organizations; and 13 individuals. A summary of comments relating to the rules and DSHS's responses follows.

Comment: One commenter requested DSHS allow stakeholders to review and submit comments on the DSHS survey guidelines that are not in the proposed neonatal rules.

Response: DSHS acknowledges the comment. DSHS is coordinating multiple training updates and opportunities to review the guidelines before the January 1, 2024, implementation date.

Comment: One commenter appreciated the PAC ad hoc workgroup serving as a resource to review the comments on the neonatal proposed rules and provide recommendations to DSHS for revisions.

Response: DSHS appreciates the comment, and no change is necessary to the rules.

Comment: One commenter requested clarification in the rules regarding the terms medical staff, personnel, and advanced practice providers.

Response: DSHS acknowledges the comment and declines to revise the rules. The standard dictionary and medical dictionary definitions are sufficient.

Comment: One commenter requested that DSHS include rule language to address adequate nurse staffing.

Response: DSHS disagrees and declines to revise the language without national standards to define required staff.

Comment: §133.182(4) and (6): Three commenters requested the definitions for "CAP" and "contingent probationary designation" to include DSHS operations expectations.

Response: DSHS acknowledges the comments and declines to revise the rule language in response to these comments. The definition for "contingent probationary designation" was removed from the rules. DSHS operations for the CAP--Corrective Action Plan are implemented by DSHS policy.

Comment: §133.182(5) and (6): Nine commenters recommended the definitions for "contingent designation" and "contingent probationary designation" be removed from the rule language to be consistent with the maternal rules or for DSHS to provide further clarification.

Response: DSHS agrees to remove both definitions, therefore clarification is not needed. The remaining paragraphs are renumbered in §133.182 due to the removal of these definitions.

Comment: §133.182(9): One commenter suggested adding "outside of a medical facility" for clarity to the "Emergency Medical Services (EMS)" definition.

Response: DSHS acknowledges the comment and declines to revise the rule language. The language is consistent with the EMS definition in §157.2 of this title, relating to Emergency Medical Care.

Comment: §133.182(13): Two commenters recommended removing "or near" from the definition of "immediately."

Response: DSHS agrees and modifies the language in renumbered §133.182(11).

Comment: §133.182(13): One commenter requested clarification of a time frame for "Immediately."

Response: DSHS acknowledges the comment and finds the rule language is sufficient. DSHS declines to revise the rule language.

Comment: §133.182(13) and (19): One commenter supports the new definitions for "immediately" and "Neonatal Program Oversight."

Response: DSHS appreciates the comment, and no change is necessary to the rules.

Comment: §133.182(19): Three commenters recommended further clarification of the definition "Neonatal Program Oversight."

Response: DSHS acknowledges the comments and declines to revise the rule. Language is consistent with the definition of the Maternal Program Oversight in §133.202(19) of this title, relating to Hospital Level of Care Designations for Maternal Care.

Comment: §133.183(c): One commenter requested the current language regarding free-standing children's hospitals be retained.

Response: DSHS agrees and replaces the stand-alone children's facility language allowing exemptions from obstetrical requirements.

Comment: §133.183(f)(3)(C): One commenter suggested removing "specific to the patient population served" from the continuing education language.

Response: DSHS acknowledges the comment and declines to revise the rule language. The language allows facilities to identify their specific neonatal populations and ensure education appropriate for patient conditions and care are provided.

Comment: §133.183(f)(3)(D) and §133.183(f)(4)(D): One commenter recommended adding language, to facilitate neonatal transports, in the Level II requirements.

Response: DSHS acknowledges the comment and declines to revise the rule language. The additional role of facilitating transports will remain with the higher-level facilities.

Comment: §§133.183(f)(3)(E), 133.183(f)(4)(E), 133.188(a)(5), and 133.189(a)(5): Two commenters stated the proposed language limits outreach education to only findings in the Quality Assessment and Performance Improvement (QAPI) Plan and process.

Response: DSHS agrees and revises the language to provide additional opportunities for outreach education.

Comment: §§133.183(f)(3)(E), 133.183(f)(4)(E), 133.188(a)(5), and 133.189(a)(5): Two commenters requested to include same and higher-level designated facilities to be included in rule language.

Response: DSHS acknowledges the comments and declines to revise the language in response to these comments. The requirement does not exclude facilities from providing outreach education to same or higher-level care facilities.

Comment: §§133.183(f)(3)(E), 133.183(f)(4)(E), 133.188(a)(5), and 133.189(a)(5): One commenter stated that providing outreach to non-designated facilities and lay birthing centers is a liability for the facilities.

Response: DSHS acknowledges the comment and declines to revise the rules in response to this comment because the facility provides education that is appropriate and applicable.

Comment: §§133.183(f)(1)(B), 133.183(f)(2)(C), 133.183(f)(3)(C), and 133.183(f)(4)(C): Two commenters suggested removing "annual" from the continuing education requirements.

Response: DSHS acknowledges the comment and declines to change the rule language. The language is consistent with §133.203 of this title.

Comment: §133.183(f)(3)(B) and §133.188(a)(2): Two commenters stated concerns regarding the availability and response times for pediatric subspecialists.

Response: DSHS acknowledges the comments and declines to revise the rules. The language requires access to consultation only and does not require a response time for the pediatric subspecialists.

Comment: §133.183(f)(4)(B) and §133.189(a)(2): Seven commenters stated concerns regarding the availability and response times for pediatric subspecialists.

Response: DSHS acknowledges the comments and declines to revise the rules. The language requires subspecialists to be available to arrive on-site at a facility which provides care for the most critical and complex neonatal patients. The language does not include response times for the pediatric subspecialist.

Comment: §133.183(g): Two commenters inquired about who determines if a facility may schedule a virtual or on-site survey.

Response: DSHS acknowledges the comments, and no change is necessary. DSHS Designation Virtual Survey Guidelines are available on the website to guide facilities in determining the method of survey.

Comment: §133.183(g)(4) and (h): Two commenters recommended modifying the language that facilities must not accept surveyors with any "known" conflict of interest.

Response: DSHS agrees and modifies the language.

Comment: §133.183(h)(1), and §133.190(b): Three commenters recommended removing the language related to surveyors not being from the same Perinatal Care Region (PCR) or Trauma Service Area (TSA) or a contiguous region of the facility's location. The concern is that the requirement will have a negative impact on the Texas hospitals and state-based survey organizations.

Response: DSHS acknowledges the comment and declines to revise the rules. DSHS is establishing requirements to limit surveyor conflicts of interest with the facility undergoing the survey. Language is consistent with §133.203(h)(1) of this title.

Comment: §133.183(h): One commenter recommended removing any responsibility from the hospital for identifying surveyor conflicts and suggested that responsibility be left solely to the survey organization.

Response: DSHS acknowledges the comment and declines to revise the rule. This language is consistent with §133.203(h) of this title.

Comment: §§133.184(a)(1)(B), 133.184(d), and 133.184(k): Seven commenters recommended DSHS extend the 90 days for a facility to implement a sustainable change in the program.

Response: DSHS appreciates the comments and declines to revise the rules. The proposed published language is: "documented evidence that the Plan of Correction (POC) was implemented within 90 days of the designation survey," replacing "demonstrated improvement." This language is consistent with §133.204(a)(1)(C) of this title.

Comment: §133.184(a)(1)(C): One commenter supported the ability for the facilities to develop and implement a plan of correction in 90 days for requirements not met.

Response: DSHS appreciates the comment, and no change is necessary to the rule.

Comment: §133.184(c): Two commenters recommended removing the language related to a change of ownership or change in physical location requirement.

Response: DSHS disagrees and declines to revise the rule. Re-designating ensures the commitment and the requirements for designation continue to be met.

Comment: §133.184(g): Two commenters requested clarification on how the designation application packet is included in the Quality Assurance and Performance Improvement (QAPI) Plan.

Response: DSHS acknowledges the comments and declines to revise the rule. Neonatal designation documents are an element of the QAPI Plan to ensure confidentiality of the information.

Comment: §133.184(j)(1): Two commenters suggested allowing facilities to post the neonatal designation status on their facility website and not post it in a public area in the facility.

Response: DSHS disagrees and declines to revise the rule. A certificate posted in the facility allows staff, patients, and visitors to view the document. Facility designation may be posted on the facility website, in addition to posting in the facility.

Comment: §133.184(p)(1) and (2): One commenter recommends DSHS develop a standard process for facility notifications.

Response: DSHS acknowledges the comment and declines to revise the rule. Regional Advisory Councils (RACs) utilize different methods of notifying healthcare entities in their region of significant changes impacting neonatal patient care.

Comment: §133.184(p)(2)(C): Three commenters shared concerns that the waiver language is not reflective of the S.B. 749 language. It is recommended to use statute language in the rule.

Response: DSHS agrees and revises the rule language to reflect the S.B. 749 language in renumbered §133.184(r)(2)(C).

Comment: §133.184(t): Twelve commenters identified concerns regarding access to peer review information by DSHS and survey organizations due to statutory confidentiality.

Response: DSHS agrees and removes the language in renumbered §133.184(v).

Comment: §133.184(u) and §133.190(f): One commenter recommended survey organizations be included in the language regarding complying with all relevant law related to the confidentiality of all facility information reviewed.

Response: DSHS agrees and revises the language in renumbered §133.184(w) and §133.190(f).

Comment: §133.185(b)(2)(A): Two commenters requested clarification that policies, procedures, and guidelines may be referenced in the Neonatal Program Plan.

Response: DSHS acknowledges the comments and declines to revise the rule. The policies, procedures, and guidelines may be referenced in the Neonatal Program Plan.

Comment: §133.185(b)(2)(D)(ii): Eight commenters stated concerns regarding the monitoring of informed consent for telemedicine and recommends removing the language.

Response: DSHS acknowledges the comments and declines to amend the language in response to these comments. Inpatient neonatal care is continuously evaluated and monitored for appropriateness and variances, for both virtual and in-person encounters, through a collaborative, multidisciplinary process.

Comment: §133.185(b)(2)(E) and §133.188(d)(19): Two commenters requested clarification related to discharge follow-up care.

Response: DSHS acknowledges the comments, and no revision is needed to the rule language. The requirements are before and during patient discharge from the facility.

Comment: §133.185(b)(2)(F): Three commenters requested the evaluation of a facility's disaster preparedness and evacuation plan be limited to the Neonatal Intensive Care Unit (NICU) or the patients directly in their care.

Response: DSHS acknowledges the comments and declines to revise the rule in response to these comments. The neonatal designation program is inclusive of all-facility inpatient neonatal care.

Comment: §133.185(b)(2)(F): One commenter requested clarification allowing the disaster response and evacuation plan to be referenced in the Neonatal Program Plan.

Response: DSHS acknowledges the comment and declines to revise the language in response to this comment, as it is sufficient. The disaster response and evacuation plan may be referenced in the Neonatal Program Plan.

Comment: §133.185(b)(2)(G): One commenter requested clarification on this requirement and if it relieves the Neonatal Medical Director (NMD) from the responsibility of reviewing credentials for medical staff and respiratory therapists.

Response: DSHS acknowledges the comment and declines to revise the rule. The NMD responsibilities are further outlined in §133.185(d) and require review of credentials.

Comment: §133.185(b)(2)(K): Two commenters requested clarification of the expected response times related to this rule.

Response: DSHS acknowledges the comments and declines to revise the rule in response to this comment. The facility defines the expected response times in their guidelines.

Comment: §133.185(b)(3)(A): Two commenters recommended removing the requirement for the Chief Executive Officer, Chief Medical Officer, and Chief Nursing Officer to implement a culture of safety.

Response: DSHS disagrees and declines to revise the rule language in response to these comments. The commitment of facility administration is required for the success of a designation program and patient safety.

Comment: §133.185(b)(3)(D): Two commenters stated concerns regarding participation in benchmarking.

Response: DSHS acknowledges the comments and declines to revise the rule in response to these comments. Benchmarking is essential for Level III and IV neonatal facilities providing care for the most critical and complex neonates.

Comment: §133.185(b)(3)(G): One commenter stated that not all facilities use telehealth.

Response: DSHS agrees and modifies the language to include "if utilized."

Comment: §133.185(c): Seven commenters stated concerns over including the medical staff bylaws.

Response: DSHS agrees and removes "bylaws" from the language.

Comment: §133.185(c)(2): Two commenters requested clarification of the participants in the team-based education and training.

Response: DSHS acknowledges the comments and declines to revise the rule. Participants include all healthcare disciplines that participate in the care of neonates. The language is consistent with the rules in this title, relating to Hospital Level of Care Designations for Maternal Care.

Comment: §133.185(d)(1): One commenter recommended adding language that allows the identified Neonatal Medical Director to delegate responsibilities to a designee.

Response: DSHS disagrees and declines to revise the rule. The facility Neonatal Medical Director responsibilities cannot be delegated.

Comment: §133.185(d)(1)(I): One commenter recommended revising language to be consistent with §133.205(d)(7) of this title, regarding leading the neonatal QAPI meetings.

Response: DSHS agrees and revises the language to "frequently lead the neonatal QAPI meetings with the NPM and participate in Neonatal Program Oversight and other neonatal meetings, as appropriate."

Comment: §133.185(e)(1): One commenter suggested additional requirements of perinatal experience for the NPM requirements.

Response: DSHS agrees and adds "experience" to the present language "for neonatal care applicable to the level of care being provided."

Comment: §133.185(e)(1): One commenter requested additional clarification for the NPM education.

Response: DSHS acknowledges the comment and declines to revise the rule in response to this comment. The NPM has requirements to both obtain education and to provide education.

Comment: §133.185(e)(3)(B): One commenter requested clarification of the NPM participation in staff and team-based training.

Response: DSHS acknowledges the comment and declines to revise the rule. The standard dictionary definition of "participation" is sufficient.

Comment: §133.185(e)(3)(E): Four commenters requested NPM exclusion from regular and active participation in neonatal care at the facility.

Response: DSHS acknowledges the comments and declines to revise the rule. The NPM must be engaged and active in neonatal care at the facility to effectively perform the duties of the position.

Comment: §§133.186(c)(3), 133.187(c)(3), 133.187(c)(12), 133.188(d)(3), and 133.189(d)(3): Three commenters stated concerns related to the NMD approval of providers. One of the commenters requested to retain "reviewed" only in the language.

Response: DSHS acknowledges the comments and modifies the language to remove "and approved."

Comment: §§133.186(c)(4)(A), 133.187(c)(11)(E), 133.188(d)(10)(F), and 133.189(d)(10)(F): Three commenters requested clarification for the preliminary and final radiology readings.

Response: DSHS acknowledges the comments and declines to revise the rules. If a preliminary reading is completed by the attending or treating physician, the final reading will be completed by a radiologist qualified to read the image.

Comment: §§133.186(c)(5), 133.187(c)(9), 133.188(d)(9), and 133.189(d)(9): One commenter suggested that immediate supervision of a pharmacy technician compounding medications for neonates may be performed virtually.

Response: DSHS acknowledges the comment and declines to revise the rules. The rule language is sufficient.

Comment: §133.187(a)(2): One commenter requested clarification for Level II subspeciality services and retaining neonatal patients.

Response: DSHS acknowledges the comment and declines to revise the rule. Medical decisions are made by the treating physician in the best interest of the patient.

Comment: §§133.187(c)(6), 133.188(d)(6), and 133.189(d)(6): Eight commenters stated concerns that a dietitian has to be available at all times, due to the "available" definition, which is unnecessary.

Response: DSHS agrees with the comments and revises the language by removing "available."

Comment: §133.187(c)(10) and §133.188(d)(12): Three commenters stated concerns regarding the requirements for speech, occupational, and physical therapists participating in neonatal care.

Response: DSHS acknowledges the comments and agrees to remove "available," which is defined as "at all times." The rule language allows the facility to define the availability and exper-

tise or qualifications of the therapists, based on the needs of the neonatal population served.

Comment: §133.187(c)(14): One commenter requested clarification if the perinatal educator has to be separate from the NPM.

Response: DSHS acknowledges the comment and declines to revise the rule. The rule language is sufficient.

Comment: §133.188(a)(4): One commenter requested to define "facilitate."

Response: DSHS acknowledges the comment and declines to revise the rule. The standard dictionary definition is sufficient.

Comment: §133.188(d)(3)(C) - (D): Eight commenters stated that interpretation of the current rule requiring additional neonatology back-up coverage would be burdensome to the facilities.

Response: DSHS acknowledges the comments and modifies the wording to clarify back-up is required when a neonatologist is covering more than one facility.

Comment: §133.188(d)(4): One commenter suggested a language revision for Level III facilities that do not perform neonatal surgery.

Response: DSHS acknowledges the comment and declines to revise the rule. The rule language is sufficient.

Comment: §133.188(d)(4) and §133.189(d)(5): Eleven commenters requested revising the pediatric surgeons' 30-minute onsite response time for urgent requests.

Response: DSHS agrees and revises the language to "within a time period consistent with current standards of professional practice and neonatal care" and included that the response times must be reviewed and monitored in the neonatal QAPI Plan.

Comment: §133.188(d)(5) and §133.189(d)(4): One commenter appreciates revisions to the current rule that required anesthesiologists to "directly provide" care to neonates.

Response: DSHS appreciates the comment, and no change is necessary to the rule language.

Comment: §133.188(d)(7)(C): One commenter recommended to remove the requirement for pathology in the operative suite for Level III facilities.

Response: DSHS acknowledges the comment and declines to revise the language. Pathology services are at the request of the operating surgeon requiring timely results during the operative procedures. Level III facilities performing applicable operative procedures must meet the requirement.

Comment: §133.188(d)(7)(B) and (C) and §133.189(d)(7)(B) and (C): Four commenters stated concerns regarding neonatal pathology and the availability of the pathologist for neonatal cases as requested.

Response: DSHS acknowledges the comments and agrees to remove "neonatal" in §133.188(d)(7)(B) and (C) and §133.189(d)(7)(B) and (C), leaving "pediatric" only to describe pathology services available. DSHS disagrees with the comments referring to a pathologist, as the rule language only states "pathology services." DSHS adds "or intra-operative frozen section" to §133.188(d)(7)(C) and §133.189(d)(7)(C), pediatric pathology services at the request of the surgeon requirement.

Comment: §133.188(d)(10)(B) and §133.189(d)(10)(B): Five commenters recommended to revise the personnel response time for urgent requests and to remove magnetic resonance imaging language.

Response: DSHS agrees with the comment and removes "magnetic resonance imaging." The language is revised to "within a time period consistent with current standards of professional practice."

Comment: §133.188(d)(10)(C) and §133.189(d)(10)(C): Three commenters requested to have "at all times" removed from the language.

Response: DSHS acknowledges the comments and declines to revise the language.

Comment: §133.188(d)(10)(E) and §133.189(d)(10)(E): Seven commenters recommended to revise the radiologist interpretation time for urgent studies.

Response: DSHS agrees and revises the language to "images consistent with the patient condition and within a time period consistent with current standards of professional practice with monitoring of variances through the neonatal QAPI Plan and process." The facility may define the method of communication from the radiologist.

Comment: §133.188(d)(10)(F) and §133.189(d)(10)(F): One commenter suggested adding language from Level I to clarify if a preliminary reading is performed.

Response: DSHS agrees and adds a new paragraph (F) for §133.188(d)(10) and §133.189(d)(10) that states "preliminary findings documented in the medical record, if preliminary reading of imaging studies pending formal interpretation is performed." The remaining paragraph is renumbered to paragraph (G).

Comment: §133.188(d)(10)(F) and §133.189(d)(10)(F): Two commenters requested revision to the QAPI language for preliminary and final readings.

Response: DSHS acknowledges the comments and declines to revise the rules. Monitoring of variances in imaging interpretations is essential for patient care.

Comment: §133.188(d)(13): Two commenters requested clarification on the "approval" of respiratory therapists by the NMD.

Response: DSHS acknowledges the comments and revises the language by removing "and approved."

Comment: §133.188(d)(18) and §133.189(d)(18): Five commenters proposed changes in the availability and staffing of lactation consultants.

Response: DSHS acknowledges the comments and declines to revise the rules. The language is consistent with §133.208(d)(28) and §133.209(d)(27) of this title.

Comment: §133.189(d)(5): Four commenters recommended revising the 30-minute response time for pediatric subspecialists.

Response: DSHS agrees and revises the language to "a time period consistent with current standards of professional practice and neonatal care," including that surgeon response times must be reviewed and monitored through the neonatal QAPI Plan.

Comment: §133.189(d)(10)(D) and (E): Three commenters requested clarification for pediatric expertise for radiologists.

Response: DSHS acknowledges the comments and declines to revise the rule in response to this comment. Pediatric expertise is determined by the neonatal program and facility, which may

include education, training, experience, and ongoing physician performance evaluations.

Comment: §133.189(d)(17): Five commenters stated concerns that the retinopathy of prematurity (ROP) follow-up includes post discharge care.

Response: DSHS acknowledges the comments and declines to revise the rule. The ROP follow up care includes inpatient treatment and discharge planning to ensure optimal patient outcomes.

Comment: §133.190(c)(1) and (2): One commenter suggested removing "collaborated with a key member of the facility's leadership" from the conflict of interest requirements.

Response: DSHS acknowledges the comment and declines to revise the language. DSHS is establishing requirements to limit surveyor conflicts of interest with the facility undergoing the survey. This language is consistent with §133.210(c)(1) of this title.

Comment: §133.191(a): Two commenters recommended removing the Perinatal Care Regions rule from the facility levels of care requirements.

Response: DSHS acknowledges the comments and declines to revise the rule. DSHS is required by Texas Health and Safety Code §241.183 to develop and adopt rules dividing the state into neonatal and maternal care regions and for facilitating transfer agreements through regional coordination.

DSHS revises §133.183(c) to replace the word "determines" with "approves." The word "facility's" is changed to "location's" for consistency within the section. The word "requirements" is replaced with "criteria" for consistency with §133.203(c) of this title.

DSHS revises §133.183(d) to "must meet department-approved requirements validated by a department-approved survey organization" and removes "demonstrate compliance with" and "have the compliance."

DSHS revises §133.183(e) and §133.185(b)(2)(I), with the word "meeting" for "compliance with." The language is revised to remove "compliance," which is a regulatory term.

DSHS revises §§133.183(f)(1)(A), 133.183(f)(2)(A), 133.186(a)(1), and 133.187(a)(1) replacing the symbol "≥" with "more than or equal to" for public communication with plain language.

DSHS revises §§133.183(f)(1)(C), (f)(3)(E), and (f)(4)(E); 133.183(g)(5); 133.185(b)(2)(D)(i); 133.185(b)(3), (b)(3)(A) and (b)(3)(D); 133.185(d)(1)(C) and (d)(1)(H); 133.185(e) and (e)(3)(F); 133.186(a)(3); 133.186(b)(3); 133.186(c)(6) and (c)(6)(D); 133.187(a)(1)(B) and (a)(2)(B); 133.187(b)(2)(C); 133.187(c)(13), (c)(13)(D), and (c)(16); 133.188(a)(5); 133.188(d)(14), (d)(14)(D), and (d)(17); 133.189(d)(14) and (d)(17) adding neonatal to QAPI plan to clarify the QAPI plan is specific to neonatal services provided in the facility.

DSHS revises §§133.183(f)(1)(C), 133.186(a)(3), 133.186(c)(6), and 133.187(a)(1)(A) and (B) replacing the symbol "≥" with "less than" for public communication with plain language.

DSHS revises §133.183(f)(2) to remove "The" to be consistent with the other Level language in §133.183(f)(1), (3), and (4).

DSHS revises the language in §133.183(g)(1) - (5) with additions of "must," "are responsible for scheduling," and "are responsible" to clarify language and for consistency with §133.203(g)(1) - (5) of this title.

DSHS revises §133.183(h) to include "had a previous working relationship with the facility or facility leaders" for consistency with §133.203(h) of this title. The time period "in the past four years" is moved to the end of the requirement and grammar is corrected to be consistent with the §133.203(h) of this title.

DSHS revises §133.183(h)(2) to state "Designation site survey summary and medical record reviews performed by a surveyor with an identified conflict of interest may not be accepted by the department" for consistency with §133.203(h)(2) of this title.

DSHS revises §133.184(a)(1) to state "the completed application packet includes:" to be consistent with §133.204(a)(1) of this title.

DSHS revises §133.184(a)(1)(A) adding "an accurate and complete" application to align with §133.204(a)(1)(A) of this title.

DSHS revises §133.184(a)(1)(B) to add "a completed" neonatal attestation for consistency with §133.204(a)(1)(B) of this title. The language "includes the requirement compliance findings" is replaced with "validates the department requirements are met." The language is revised to remove "compliance findings," which is a regulatory term.

DSHS revises the language in §133.184(a)(1)(C) to clarify if a facility has three or more department-approved designation requirements defined as "not met," the facility must contact the department within 10 business days to discuss the Plan of Correction (POC). This language is consistent with the §133.204(a)(1)(C) of this title.

DSHS adds "if required by the department" to §133.184(a)(1)(D) to clarify that the POC is not required for every application packet.

DSHS revises §133.184(a)(1)(D)(v) to state "how the corrective actions will be monitored" remove " a statement on" and change "action" to "actions" for consistent language with §133.204(a)(1)(D)(v) of this title.

DSHS revises §133.184(a)(2)(A)(i) to replace the symbol "≤" with "less than or equal to" for public communication with plain language.

DSHS revises §133.184(a)(2)(A)(ii) to replace the symbol ">" with "more than" for public communication with plain language.

DSHS revises §133.184(c) adding "The neonatal designation renewal process, or a request" to replace "A facility requesting." The word "experiencing" was removed and replaced with "or" and "require the facility to" is added to replace "must." The language is consistent with §133.204(c) of this title.

DSHS revises §133.184(d) to replace "renewal designations" with "designation renewals" to be consistent with §133.204(d) of this title.

DSHS revises §133.184(e) removing "being approved for" and replacing it with "a" and replacing "by the department" with "approval" to be consistent with §133.204(e) of this title.

DSHS adds §133.184(f) with "The facility must seek neonatal designation renewal to maintain continual designation and prevent an interruption in designation" for consistent language with §133.204(f) of this title. The remaining subsections for this section are renumbered due to this addition.

DSHS revises renumbered §133.184(g) to remove "timely and" to be consistent with §133.204(g) of this title.

DSHS revises renumbered §133.184(h) to remove "and all relevant laws related to the confidentiality of such records" to be consistent with §133.204(h) of this title.

DSHS revises renumbered §133.184(j) adding "and this designation" to replace "which" to be consistent with §133.204(j) of this title.

DSHS revises renumbered §133.184(l) moving "required documents" and "to continue the designation process" together. Words "and" and "with the" are added to be consistent with §133.204(l) of this title. DSHS revises the language in renumbered §133.184(m) adding "will approve" in place of "reviews and approves" and corrected the tense of "demonstrated" to "demonstrates" to be consistent with §133.204(m) of this title.

DSHS revises the language in renumbered §133.184(n) with "the designation requirement for that level of care designation" to be consistent with §133.204(n) of this title.

DSHS adds §133.184(o) with "If a facility does not meet the designation requirement for the level of designation requested, the department will designate the facility at the highest level for which designation requirements are met," for consistent language with §133.204(o) of this title.

DSHS revises renumbered §133.184(p) adding "designation" before requirements, changing "notify" to "provide written notification" and adding "provide a Corrective Action Plan (CAP) to assist the facility in meeting the designation requirements. The CAP may include requiring the facility to have a focused survey or a complete re-survey." The language revisions are consistent with §133.204(p) of this title.

DSHS revises the language in renumbered §133.184(q) to replace the word "determined" with "awarded." The language "recommends" and "panel will recommend" is added to §133.184(q)(2) and (3). The word "decision" is replaced with "recommendation" in §133.184(q)(2) and (4). The word "decision" was removed in §133.184(q)(5). The language revisions are consistent with §133.204(q), (q)(2), (q)(3), (q)(4), and (q)(5) of this title.

DSHS revises renumbered §133.184(r)(2)(C) language to remove "may" and add "facility meets all other designation requirements for the level of care designation and the," for consistent language with §133.204(r)(2)(C) of this title.

DSHS removes §133.184(r)(2)(C)(iv) and relocates and revises this requirement to §133.184(r)(2)(C) to be consistent with §133.204(r)(2)(C) of this title.

DSHS revises §133.185(b)(1) to add "and approval" to be consistent with the §133.205(b) of this title.

DSHS revises §§133.185(b)(2)(D)(ii), 133.185(d)(1)(F)(i), 133.185(d)(2)(A) and 133.185(e)(3)(D)(i) by replacing the word "compliance" with "variances." The language was revised to remove "compliance," which is a regulatory term.

DSHS revises §133.185(b)(2)(E) to written guidelines for "follow-through planning, discharge instructions." The language was revised to remove "compliance" which is a regulatory term.

DSHS revises §133.185(b)(2)(F) to change "hospital's" to "hospital" and adds "and this process" to replace "which" to align with §133.205(b)(2)(G) of this title.

DSHS revises §§133.185(b)(2)(H) and 133.185(d)(1)(B) changing "competency" to "competencies" for consistency in the rule language.

DSHS revises §133.185(b)(2)(I) adding "meeting" to replace "compliance with." The language was revised to remove "compliance," which is a regulatory term.

DSHS revises §133.185(b)(2)(K) to include "support" personnel and "lactation" to align with §133.206 and §133.207 of this title.

DSHS revises §133.185(b)(3)(A) changing "available" to "allocated" to align with §133.205(b)(3)(A) of this title.

DSHS revises §133.185(b)(3)(B) to replace "and monitor until the needed change is sustained" to "An action plan will track and analyze data through resolution or correction of the identified variance" to be consistent with §133.205(b)(3)(B) of this title.

DSHS revises §133.185(b)(3)(D) to add "All neonatal facilities must participate in a neonatal data initiative." The language is added to support the stakeholders request for state-wide data to support PAC decisions.

DSHS revises §133.185(b)(3)(F) moving "QAPI" between "regional" and "initiatives" to define the QAPI is for regional initiatives.

DSHS revises §133.185(b)(3)(G) adding "reviewed and reported by Neonatal Program Oversight" that monitor "and ensure the provision of services or procedures through" telehealth and telemedicine, "if utilized, is in accordance with the" standards of care "applicable to the provision of the same service or procedure in an in-person setting" to align with §133.205(b)(3)(G) of this title.

DSHS revises §133.185(d)(1)(C) adding "stabilization, operative intervention(s) if applicable, through discharge and review variances in care" to be consistent with §133.205(d)(3) of this title.

DSHS revises §133.185(d)(1)(F)(iv) to include "medical staff, advanced practice providers, and personnel competencies" to further clarify which staff are included for competencies, education, and training.

DSHS revises §133.185(d)(1)(I) to "frequently lead the neonatal QAPI meetings with the NPM and participate in the Neonatal Program Oversight and other neonatal meetings as appropriate" to be consistent with §133.205(d)(7) of this title.

DSHS revises §133.185(d)(1)(K) and §133.185(e)(3)(H) adding "develop and." The language was revised to maintain the action of developing relationships due to personnel changes in the MMD and MPM roles for designation.

DSHS revises §133.185(e)(1) to add "and experience" to the language to align with §133.205(e)(1) of this title.

DSHS revises §133.185(e)(3)(C) to replace "track" with "monitor." The language is revised to be consistent with §133.205(b)(2)(E)(i) and (ii) of this title, related to telehealth and telemedicine.

DSHS revises §133.185(e)(3)(G) to "frequently lead the neonatal QAPI meetings and participate in Neonatal Program Oversight and other neonatal meetings as appropriate" to be consistent with §133.205(e)(5) of this title.

DSHS revises §133.186(b)(1) adding "and with privileges in neonatal care" to be consistent with §133.206(b)(1) of this title, which includes "privileges in maternal care."

DSHS revises §133.186(b)(3) and §133.187(b)(2)(C) adding "demonstrates" to replace "maintains" to be consistent with §§133.206(b)(2) and §133.207(b)(2) of this title.

DSHS revises §133.186(b)(4) and §133.187(b)(2)(E) replacing "annually" with "annual" and "must complete annual" to be consistent with §133.206(b)(4) and §133.207(b)(3) of this title.

DSHS revises §§133.186(c)(3), 133.187(c)(3), and 133.188(d)(3) moving "must" to the additional list of requirements to clarify the grammar.

DSHS adds "The facility must have" to §133.186(c)(4) to correct grammar.

DSHS revises §§133.186(c)(6)(D), 133.187(c)(13)(D) 133.188(d)(14)(D), and 133.189(d)(14)(D) adding "Variances from these standards are monitored through the neonatal QAPI Plan and process" to replace "Compliance to this staffing requirement is monitored through the QAPI Plan." The language was revised to remove "compliance," which is a regulatory term.

DSHS revises §§133.187(c)(6) language to "Dietitian or nutritionist with appropriate training and experience in neonatal nutrition provides services for the population served" to be consistent with the §133.207 of this title.

DSHS revises §§133.187(c)(18), 133.188(d)(19), and 133.189(d)(19) to replace "follow-up" with "follow-through" because the standard definition for "follow-through" is more accurate for the requirement.

DSHS revises §133.188(d)(6) language to "Dietitian or nutritionist with appropriate training and experience in neonatal nutrition, plans diets that meet the needs of the neonate/infant and provides services for the population served" to be consistent with the §133.208 of this title.

DSHS revises §133.188(d)(12)(A) and §133.189(d)(12)(A) replacing "manage" with "recommend management of" and adding "as appropriate for the patient's condition" to align with the neonatal clinical practices for the population served by the facility.

DSHS revises §133.189(d)(3)(A) - (C) adding "must" and replacing "annually" with "annual" in (B) to be consistent with §133.209 of this title.

DSHS adds "must ensure the facility has a back-up neonatal provider if the neonatologist is not immediately available" as §133.189(d)(3)(C). The addition for Level IV is consistent with Level I, II, and III requirements to ensure a back-up for the primary neonatologist if they are unavailable.

DSHS revises §133.189(d)(6) language to "Dietitian or nutritionist with appropriate training and experience in neonatal nutrition, plans diets that meet the needs of the neonate/infant and critically ill neonatal patient and provides services for the population served" to be consistent with the §133.209 of this title.

DSHS revises §133.189(d)(12) to add "infant" and remove "be available to" to align language with §133.188(d)(12).

DSHS revises §133.190(a)(2)(A) - (D), (a)(3)(A) - (D) and (a)(4)(A) - (D) to correct grammar by changing "has" to "have," "is" to "are" and "meets" to "meet."

DSHS adds "in the facility" in §133.190(a)(3) to clarify that a pediatric surgeon is included in the Level III survey team if the facility performs neonatal surgery.

DSHS adds "or this subchapter" in §133.190(f) to ensure all information and materials required in the Neonatal Levels of Care rule, for review by DSHS or a survey organization, are considered confidential under applicable laws to be consistent with the §133.210 of this title.

STATUTORY AUTHORITY

The amendments and new rule are authorized by Texas Health and Safety Code, Chapter 241, which provides DSHS with the authority to adopt rules establishing the levels of care for neonatal care, establish a process of assignment or amendment of the levels of care to hospitals, divide the state into Perinatal Care Regions, and facilitate transfer agreements through regional coordination; and by Texas Government Code §531.0055, and Texas Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

§133.182. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) Attestation--A written statement, signed by the chief executive officer of the facility, verifying the results of a self-survey represent a complete and accurate assessment of the facility's capabilities required in this subchapter.

(2) Available--Relating to staff who can be contacted for consultation at all times without delay.

(3) Birth weight--The weight of the neonate recorded at time of birth.

(A) Low birth weight--Birth weight less than 2500 grams (5 lbs., 8 oz.);

(B) Very low birth weight (VLBW)--Birth weight less than 1500 grams (3 lbs., 5 oz.); and

(C) Extremely low birth weight (ELBW)--Birth weight less than 1000 grams (2 lbs., 3 oz.).

(4) CAP--Corrective Action Plan. A plan for the facility developed by the department that describes the actions required of the facility to correct identified deficiencies to ensure the applicable designation requirements are met.

(5) Department--The Texas Department of State Health Services.

(6) Designation--A formal recognition by the department of a facility's neonatal care capabilities and commitment for a period of three years.

(7) EMS--Emergency medical services. Services used to respond to an individual's perceived need for immediate medical care.

(8) Focused survey--A department-defined, modified facility survey by a department-approved survey organization or the department. The specific goal of this survey is to review designation requirements identified as not met to resolve a contingent designation or requirement deficiencies.

(9) Gestational age--The age of a fetus or embryo determined by the amount of time that has elapsed since the first day of the mother's last menstrual period or the corresponding age of the gestation as estimated by a physician through a more accurate method.

(10) High-risk infant--A newborn that has a greater chance of complications because of conditions that occur during fetal development, pregnancy conditions of the mother, or problems that may occur during labor or birth.

(11) Immediately--Able to respond without delay, commonly referred to as STAT.

(12) Infant--A child from birth to one year of age.

(13) Inter-facility transport--Transfer of a patient from one health care facility to another health care facility.

(14) Lactation consultant--A health care professional who specializes in the clinical management of breastfeeding.

(15) Maternal--Pertaining to the mother.

(16) NCPAP--Nasal continuous positive airway pressure.

(17) Neonatal Program Oversight--A multidisciplinary process responsible for the administrative oversight of the neonatal program and having the authority for approving the defined neonatal program's policies, procedures, and guidelines for all phases of neonatal care provided by the facility, to include defining the necessary staff competencies, monitoring to ensure neonatal designation requirements are met, and the aggregate review of the neonatal Quality Assessment and Performance Improvement (QAPI) initiatives and outcomes. Neonatal Program Oversight may be performed through the neonatal program's performance improvement committee, multidisciplinary oversight committee, or other structured means.

(18) Neonate--An infant from birth through 28 completed days.

(19) NMD--Neonatal Medical Director.

(20) NPM--Neonatal Program Manager.

(21) NRP--Neonatal Resuscitation Program. A resuscitation course developed and administered jointly by the American Heart Association and the American Academy of Pediatrics.

(22) On-site--At the facility and able to arrive at the patient bedside for urgent requests.

(23) PCR--Perinatal Care Region. The PCRs are established for descriptive and regional planning purposes. The PCRs are geographically divided by counties and are integrated into the existing 22 Trauma Service Areas (TSAs) and the applicable Regional Advisory Council (RAC) of the TSA provided in §157.122 of this title (relating to Trauma Services Areas) and §157.123 of this title (relating to Regional Emergency Medical Services/Trauma Systems).

(24) Perinatal--Of, relating to, or being the period around childbirth, especially the five months before and one month after birth.

(25) POC--Plan of Correction. A report submitted to the department by the facility detailing how the facility will correct any deficiencies cited in the neonatal designation site survey summary or documented in the self-attestation.

(26) Premature/prematurity--Birth at less than 37 weeks of gestation.

(27) QAPI Plan--Quality Assessment and Performance Improvement Plan. QAPI is a data-driven and proactive approach to quality improvement. It combines two approaches - Quality Assessment (QA) and Performance Improvement (PI). QA is a process used to ensure services are meeting quality standards and assuring care reaches a defined level. PI is the continuous study and improvement process designed to improve system and patient outcomes.

(28) RAC--Regional Advisory Council as described in §157.123 of this title.

(29) Supervision--Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity.

(30) Telehealth service--A health service, other than a telemedicine medical service, delivered by a health professional licensed, certified, or otherwise entitled to practice in this state and acting within the scope of the health professional's license, certification, or entitlement to a patient at a different physical location than the health professional using telecommunications or information technology as defined in Texas Occupations Code §111.001.

(31) Telemedicine medical service--A health care service delivered by a physician licensed in this state, or health professional acting under the delegation and supervision of a physician licensed in this state and acting within the scope of the physician's or health professional's license to a patient at a different physical location than the physician or health professional using telecommunications or technology as defined in Texas Occupations Code §111.001.

(32) TSA--Trauma Service Area as described in §157.122 of this title.

(33) Urgent--Requiring action or attention within 30 minutes of notification.

§133.183. General Requirements.

(a) The department reviews the applicant documents and approves the appropriate level of facility designation.

(b) A facility is defined under this subchapter as a single location where inpatients receive hospital services; or each location, if there are multiple buildings where inpatients receive hospital services and are covered under a single hospital license.

(c) Each location must be considered separately for designation and the department approves the designation level for each location based on the location's ability to demonstrate designation criteria are met. A stand-alone children's facility that does not provide obstetrical services is exempt from obstetrical requirements.

(d) The department determines requirements for the levels of neonatal designation. Facilities seeking Levels II, III, and IV neonatal designation must meet department-approved requirements validated by a department-approved survey organization.

(e) Facilities seeking Level I neonatal designation must submit a self-survey and attest to meeting department-approved requirements.

(f) The four levels of neonatal designation are:

(1) Level I (Well Care). The Level I neonatal designated facility must:

(A) provide care for mothers and their infants of generally more than or equal to 35 weeks gestational age who have routine, transient perinatal problems;

(B) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served; and

(C) provide the same level of care that the neonate would receive at a higher-level designated neonatal facility and complete an in-depth critical review and assessment of the care provided to these infants through the neonatal QAPI Plan and process if an infant less than 35 weeks gestational age is retained.

(2) Level II (Special Care). The Level II neonatal designated facility must:

(A) provide care for mothers and their infants of generally more than or equal to 32 weeks gestational age and birth weight

more than or equal to 1500 grams who have physiologic immaturity or problems that are expected to resolve rapidly and are not anticipated to require subspecialty services on an urgent basis;

(B) provide care, either by including assisted endotracheal ventilation for less than 24 hours or nasal continuous positive airway pressure (NCPAP) until the infant's condition improves, or arrange for appropriate transfer to a higher-level designated facility; and

(C) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served.

(3) Level III (Neonatal Intensive Care). The Level III neonatal designated facility must:

(A) provide care for mothers and comprehensive care for their infants of all gestational ages with mild to critical illnesses or requiring sustained life support;

(B) ensure access to consultation to a full range of pediatric medical subspecialists and pediatric surgical specialists, and the capability to perform major pediatric surgery on-site or at another appropriate neonatal designated facility;

(C) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served;

(D) facilitate neonatal transports; and

(E) provide outreach education related to trends identified through the neonatal QAPI Plan, specific requests, and system needs to lower-level neonatal designated facilities, and as appropriate and applicable, to non-designated facilities, birthing centers, independent midwife practices, and prehospital providers.

(4) Level IV (Advanced Neonatal Intensive Care). The Level IV neonatal designated facility must:

(A) provide care for mothers and comprehensive care for their infants of all gestational ages with the most complex and critical medical and surgical conditions or requiring sustained life support;

(B) ensure access to a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists available to arrive on-site, in person for consultation and care, and the capability to perform major pediatric surgery, including the surgical repair of complex conditions on-site;

(C) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served;

(D) facilitate neonatal transports; and

(E) provide outreach education related to trends identified through the neonatal QAPI Plan, specific requests, and system needs to lower-level neonatal designated facilities, and as appropriate and applicable, to non-designated facilities, birthing centers, independent midwife practices, and prehospital providers.

(g) Facilities seeking neonatal designation must undergo an on-site or virtual survey as outlined in this section and:

(1) are responsible for scheduling a neonatal designation survey through a department-approved survey organization;

(2) must notify the department of the neonatal designation survey date;

(3) are responsible for expenses associated with the neonatal designation survey;

(4) must not accept surveyors with any known conflict of interest; and

(5) must provide the survey team access to records and documentation regarding the neonatal QAPI Plan and process related to neonatal patients. The department may determine that failure by a facility to provide access to these records does not meet the requirements of this subchapter.

(h) If a known conflict of interest is present for the facility seeking neonatal designation, the facility must decline the assigned surveyor through the surveying organization. A conflict of interest exists when a surveyor has a direct or indirect financial, personal, or other interest which would limit or could reasonably be perceived as limiting the surveyor's ability to serve in the best interest of the public. The conflict of interest may include a surveyor who personally trained a key member of the facility's leadership in residency or fellowship, collaborated with a key member of the facility's leadership team professionally, participated in a designation consultation with the facility, had a previous working relationship with the facility or facility leaders, or conducted a designation survey for the facility within the past four years.

(1) Surveyors cannot be from the same PCR or TSA region or a contiguous region of the facility's location.

(2) Designation site survey summary and medical record reviews performed by a surveyor with an identified conflict of interest may not be accepted by the department.

(i) The department, at its sole discretion, may appoint an observer to accompany the survey team with the observer costs borne by the department.

(j) The survey team evaluates the facility's evidence that department-approved designation requirements are met and documents all requirements that are not met in the neonatal designation site survey summary and medical record reviews.

§133.184. Designation Process.

(a) A facility seeking neonatal designation or renewal of designation must submit a completed application packet.

(1) The completed application packet includes:

(A) an accurate and complete neonatal designation application for the requested level of designation;

(B) a completed neonatal attestation and self-survey report for Level I applicants, or the documented neonatal designation site survey summary that validates the department requirements are met and the medical record reviews for Levels II, III and IV applicants, submitted to the department no later than 90 days after the neonatal designation site survey date;

(C) if the facility has three or more department-approved designation requirements that are defined as not met in the neonatal designation site survey summary, the facility must contact the department's designation unit within 10 business days to discuss the Plan of Correction (POC);

(D) the POC, if required by the department, which must include:

(i) a statement of the cited designation requirement not met;

(ii) a statement describing the corrective action taken by the facility seeking neonatal designation to meet the requirement;

(iii) the title of the individuals responsible for ensuring the corrective actions are implemented;

(iv) the date the corrective actions were implemented;

(v) how the corrective actions will be monitored; and

(vi) documented evidence that the POC was implemented within 90 days of the designation survey;

(E) written evidence of annual participation in the applicable PCRs; and

(F) any subsequent documents submitted by the date requested by the department.

(2) The application includes full payment of the non-refundable, non-transferrable designation fee listed:

(A) Level I neonatal facility applicants, the fees are as follows:

(i) less than or equal to 100 licensed beds, the fee is $250.00; or

(ii) more than 100 licensed beds, the fee is $750.00.

(B) Level II neonatal facility applicants, the fee is $1,500.00.

(C) Level III neonatal facility applicants, the fee is $2,000.00.

(D) Level IV neonatal facility applicants, the fee is $2,500.00.

(b) The application will not be processed if a facility seeking neonatal designation fails to submit the required application documents and total designation fee.

(c) The neonatal designation renewal process, or a request to designate at a different level of care, or a change in ownership, or a change in physical address require the facility to notify the department and submit a complete designation application packet outlined in subsection (a)(1) and (2) of this section.

(d) The facility must submit the required documents described in subsection (a)(1) and (2) of this section to the department no later than 90 days before the facility's current neonatal designation expiration date for all designation renewals.

(e) The facility has the right to withdraw its application for neonatal designation any time before a designation approval.

(f) The facility must seek neonatal designation renewal to maintain continual designation and prevent an interruption in designation.

(g) The facility's neonatal designation will expire if the facility fails to provide a complete neonatal designation application packet to the department.

(h) The neonatal designation application packet in its entirety, including any recommendations or follow-up from the department, and any opportunities for improvement, must be a written element of the facility's neonatal QAPI Plan and must be reviewed through this process, which is all subject to confidentiality as described in Texas Health and Safety Code, §241.184, Confidentiality; Privilege.

(i) The department reviews the application packet to determine and approve the facility's level of neonatal designation.

(j) The department defines the final neonatal designation level awarded to the facility, and this designation may be different than the level requested based on the neonatal designation site survey summary.

(k) If the department determines the facility meets the requirements for neonatal designation, the department provides the facility with a designation award letter and a designation certificate.

(1) The facility must display its neonatal designation certificate in a public area of the licensed premises that is readily visible to patients, employees, and visitors.

(2) The facility must not alter the neonatal designation certificate. Any alteration voids neonatal designation for the remainder of that designation period.

(l) The survey organization must provide the facility with a written, signed neonatal designation site survey summary, including medical record reviews, regarding their evaluation and validation of the facility's demonstration that neonatal designation requirements are met. The neonatal designation site survey summary must be forwarded to the facility no later than 30 days after the completion date of the survey. The facility is responsible for submitting a copy of the neonatal designation site survey summary and medical record reviews to the department, with the required documents to continue the designation process, within 90 days of completion of the site survey.

(m) The department will approve designation of a facility that demonstrates the requirements are met.

(n) A neonatal level of care designation must not be denied to a facility that meets the designation requirements for that level of care designation.

(o) If a facility does not meet the designation requirements for the level of designation requested, the department will designate the facility at the highest level for which designation requirements are met.

(p) If the department determines a facility does not meet the designation requirements for the level of designation requested, the department must provide written notification to the facility of the designation requirements not met and provide a Corrective Action Plan (CAP) to assist the facility in meeting the designation requirements. The CAP may include requiring the facility to have a focused survey or a complete re-survey.

(1) The facility must submit to the department reports as required and outlined in the CAP. The department may require a second survey to ensure they meet the designation requirements. The cost of the second survey will be at the expense of the facility.

(2) If the department substantiates actions taken by the facility demonstrating documented evidence that designation requirements are met, the department removes the contingencies.

(q) If a facility disagrees with the designation level awarded by the department, it may request an appeal in writing to the EMS/Trauma Systems Section Director not later than 30 days after the designation award. The written appeal must be from the facility's Chief Executive Officer, Chief Medical Officer, or Chief Nursing Officer with documented evidence of how the facility meets the requirements for the requested designation level.

(1) The EMS/Trauma Systems Section will establish a three-person appeal panel and follow approved appeal panel guidelines to assess the facility's designation appeal as referenced in Texas Health and Safety Code §241.1836.

(2) If the designation appeal panel recommends the original determination, the EMS/Trauma Systems Section Director will give

written notice of such to the facility not later than 30 days after the appeal panel's recommendation.

(3) If the designation appeal panel disagrees with the department's original designation determination, the panel will recommend the appropriate level of neonatal designation to the department.

(4) If a facility disagrees with the designation appeal panel's recommendation regarding its designation level, the facility can request a second appeal review with the department's Associate Commissioner for Consumer Protection Division. If the Associate Commissioner upholds the designation appeal panel's recommendation, the designation status will remain the same. If the Associate Commissioner disagrees with the designation appeal panel's recommendation, the Associate Commissioner will define the appropriate level and award designation. The department will send a notification letter of the second appeal decision within 30 days of receiving the second appeal request.

(5) If the facility continues to disagree with the second level of appeal, the facility has a right to a hearing in the manner referenced in §133.121 of this title (relating to Enforcement Action).

(r) Exceptions and Notifications

(1) A designated neonatal facility must provide written or electronic notification of any significant change to the neonatal program impacting patient care. The notification must be provided to the following:

(A) all emergency medical services (EMS) providers that transfer neonatal patients to or from the designated neonatal facility;

(B) the hospitals to which it customarily transfers out or transfers in neonatal patients;

(C) applicable PCRs and RACs; and

(D) the department.

(2) If the designated neonatal facility is unable to meet the requirements to maintain its current designation, it must submit to the department a POC as described in subsection (a)(1)(D) of this section, and a request for a temporary exception to the designation requirements. Any request for an exception must be submitted in writing from the facility's Chief Executive Officer and define the facility's timeline to meet the designation requirements. The department reviews the request and the POC, and either grants the exception with a specific timeline based on the public interest, geographic maternal care capabilities, and access to care, or denies the exception. If the facility is not granted an exception or it does not meet the designation requirements at the end of the exception period, the department will elect one of the following:

(A) re-designate the facility at the level appropriate to its revised capabilities;

(B) outline an agreement with the facility to satisfy all designation requirements for the level of care designation within a time specified under the agreement, which may not exceed the first anniversary of the effective date of the agreement; or

(C) waive one specific designation requirement for a level of care designation if the facility meets all other designation requirements for the level of care designation and the department determines the waiver is justified considering:

(i) the expected impact on accessibility of neonatal care in the geographic area served by the facility if the waiver is not granted and the expected impact on the quality of care and patient safety; or

(ii) whether these services can be met by other facilities in the area or with telehealth/telemedicine services.

(3) Waivers expire with the expiration of the current designation but may be renewed. The department may specify any conditions for ongoing reporting during this time.

(4) The department maintains a current list on its internet website of facilities that have contingency agreements or an approved waiver with the department and an aggregated list of the designation requirements conditionally met or waived.

(5) Facilities that have contingency agreements or an approved waiver with the department must post on the facility's internet website the nature and general terms of the agreement.

(s) An application for a higher or lower level of neonatal designation may be submitted to the department at any time.

(1) A designated neonatal facility that is increasing its neonatal capabilities may choose to apply for a higher-level of designation at any time. The facility must follow the designation process as described in subsection (a)(1) and (2) of this section to apply for the higher-level.

(2) A designated neonatal facility that is unable to maintain the facility's current level of neonatal designation may choose to apply for a lower level of designation at any time.

(t) If the facility is relinquishing its neonatal designation, the facility must provide 30 days written, advance notice of the relinquishment to the department, the applicable PCRs/RACs, EMS providers, and facilities it customarily transfers out or transfers in neonatal patients. The facility is responsible for continuing to provide neonatal care services or ensuring a plan for neonatal care continuity for the 30 days following the written notice of relinquishing its neonatal designation.

(u) A hospital providing neonatal services must not use the terms "designated neonatal facility" or similar terminology in its signs, advertisements, facility internet website, social media, or in the printed materials and information it provides to the public, unless the facility is currently designated at that level of neonatal care.

(v) During a virtual, on-site, or focused designation review, conducted by the department or survey organization, the department or surveyor has the right to review and evaluate neonatal patient records, neonatal multidisciplinary QAPI Plan documents, and any action specific to improving neonatal care and outcomes, as well as any other documents relevant to neonatal care in a designated neonatal facility or facility seeking neonatal designation to validate designation requirements are met.

(w) The department and survey organization will comply with all relevant laws related to the confidentiality of records.

(x) The department may deny, suspend, or revoke designation if a designated neonatal facility ceases to provide services to meet or maintain the designation requirements of this section.

§133.185. Program Requirements.

(a) Neonatal Program Philosophy. Designated facilities must have a family-centered philosophy. Parents must have reasonable access to their infants at all times and be encouraged to participate in the care of their infants. The facility environment for perinatal care must meet the physiologic and psychosocial needs of the mothers, infants, and families.

(b) Neonatal Program Plan. The facility must develop a written neonatal operational plan for the neonatal program that includes a detailed description of the scope of services and clinical resources

available for all neonatal patients, mothers, and families. The plan must define the neonatal patient population evaluated, treated, transferred, or transported by the facility consistent with clinical guidelines based on current standards of neonatal practice ensuring the health and safety of patients.

(1) The written Neonatal Program Plan must be reviewed and approved by Neonatal Program Oversight and be submitted to the facility's governing body for review and approval. The governing body must ensure the requirements of this section are implemented and enforced.

(2) The written Neonatal Program Plan must include, at a minimum:

(A) clinical guidelines based on current standards of neonatal practice, and policies and procedures that are adopted, implemented, and enforced by the neonatal program;

(B) a process to ensure and validate these clinical guidelines based on current standards of neonatal practice, policies, and procedures, are reviewed and revised a minimum of every three years;

(C) written triage, stabilization, and transfer guidelines for neonatal patients that include consultation and transport services;

(D) the role and scope of telehealth/telemedicine practices, if utilized, including:

(i) documented and approved written policies and procedures that outline the use of telehealth/telemedicine for inpatient hospital care or for consultation, including appropriate situations, scope of care, and documentation that is monitored through the neonatal QAPI Plan and process; and

(ii) written and approved procedures to gain informed consent from the patient or designee for the use of telehealth/telemedicine, if utilized, that are monitored for variances;

(E) written guidelines for discharge planning instructions and appropriate follow-up appointments for all neonates/infants;

(F) written guidelines for the hospital disaster response, including a defined neonatal evacuation plan and process to relocate mothers and infants to appropriate levels of care with identified resources, and this process must be evaluated annually to ensure neonatal care can be sustained and adequate resources are available;

(G) written minimal education and credentialing requirements for all staff participating in the care of neonatal patients, which are documented and monitored by the managers who have oversight of staff;

(H) written requirements for providing continuing staff education, including annual competencies and skills assessment that is appropriate for the patient population served, which are documented and monitored by the managers who have oversight of staff;

(I) documentation of meeting the requirement for a perinatal staff registered nurse to serve as a representative on the nurse staffing committee under §133.41 of this title (relating to Hospital Functions and Services);

(J) measures to monitor the availability of all necessary equipment and services required to provide the appropriate level of care and support for the patient population served; and

(K) documented guidelines for consulting support personnel with knowledge and skills in breastfeeding and lactation, which includes expected response times, defined roles, responsibilities, and expectations.

(3) The facility must have a documented and approved neonatal QAPI Plan.

(A) The Chief Executive Officer, Chief Medical Officer, and Chief Nursing Officer must implement a culture of safety for the facility and ensure adequate resources are allocated to support a concurrent, data-driven neonatal QAPI Plan.

(B) The facility must demonstrate that the neonatal QAPI Plan consistently assesses the provision of neonatal care provided. The assessment must identify variances in care, the impact to the patient, and the appropriate levels of review. This process must identify opportunities for improvement and develop a plan of correction to address the variances in care or the system response. An action plan will track and analyze data through resolution or correction of the identified variance.

(C) The neonatal program must measure, analyze, and track performance through defined quality indicators, core performance measures, and other aspects of performance that the facility adopts or develops to evaluate processes of care and patient outcomes. Summary reports of these findings are reported through the Neonatal Program Oversight.

(D) All neonatal facilities must participate in a neonatal data initiative. Level III and IV neonatal facilities must participate in benchmarking programs to assess their outcomes as an element of the neonatal QAPI Plan.

(E) The Neonatal Medical Director (NMD) must have the authority to make referrals for peer review, receive feedback from the peer review process, and ensure neonatal physician representation in the peer review process for neonatal cases.

(F) The NMD and Neonatal Program Manager (NPM) must participate in PCR meetings, regional QAPI initiatives, and regional collaboratives, and submit requested data to assist with data analysis to evaluate regional outcomes as an element of the facility's neonatal QAPI Plan.

(G) The facility must have documented evidence of neonatal QAPI summary reports reviewed and reported by Neonatal Program Oversight that monitor and ensure the provision of services or procedures through telehealth and telemedicine, if utilized, is in accordance with the standards of care applicable to the provision of the same service or procedure in an in-person setting.

(H) The facility must have documented evidence of neonatal QAPI summary reports to support that aggregate neonatal data are consistently reviewed to identify developing trends, opportunities for improvement, and necessary corrective actions. Summary reports must be provided through the Neonatal Program Oversight, available for site surveyors, and submitted to the department as requested.

(c) Medical Staff. The facility must have an organized, effective neonatal program that is recognized by the facility's medical staff and approved by the facility's governing body.

(1) The credentialing of the neonatal medical staff must include a process for the delineation of privileges for neonatal care.

(2) The neonatal medical staff must participate in ongoing staff and team-based education and training in the care of the neonatal patient.

(d) Medical Director. There must be an identified NMD and an identified Transport Medical Director (TMD) if the facility has its own transport program. The NMD and TMD must be credentialed by the facility for treatment of neonatal patients and have their responsi-

bilities and authority defined in a job description. The NMD and TMD must maintain a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course.

(1) The NMD is responsible for the provision of neonatal care services and must:

(A) examine qualifications of medical staff and advanced practice providers requesting privileges to participate in neonatal/infant care, and make recommendations to the appropriate committee for such privileges;

(B) ensure neonatal medical staff and advanced practice provider competencies in managing neonatal emergencies, complications, and resuscitation techniques;

(C) monitor neonatal patient care from transport, to admission, stabilization, and operative intervention(s), as applicable, through discharge, and review variances in care through the neonatal QAPI Plan;

(D) participate in ongoing neonatal staff and team-based education and training in the care of the neonatal patient;

(E) oversee the inter-facility neonatal transport as appropriate;

(F) collaborate with the NPM, maternal teams, consulting physicians, and nursing leaders and units providing neonatal care to include developing, implementing, or revising:

(i) written policies, procedures, and guidelines for neonatal care that are implemented and monitored for variances;

(ii) the neonatal QAPI Plan, specific reviews, and data initiatives;

(iii) criteria for transfer, consultation, or higher-level of care; and

(iv) medical staff, advanced practice providers, and personnel competencies, education, and training;

(G) participate as a clinically active and practicing physician in neonatal care at the facility where medical director services are provided;

(H) ensure that the neonatal QAPI Plan is specific to neonatal/infant care, is ongoing, data driven, and outcome based;

(I) frequently lead the neonatal QAPI meetings with the NPM and participate in the Neonatal Program Oversight and other neonatal meetings, as appropriate;

(J) maintain active staff privileges as defined in the facility's medical staff bylaws; and

(K) develop and maintain collaborative relationships with other NMDs of designated neonatal facilities within the applicable PCR.

(2) The TMD is responsible for the facility neonatal transport program and must:

(A) collaborate with the transport team to develop, revise, and implement written policies, procedures, and guidelines, for neonatal care that are implemented and monitored for variances;

(B) participate in ongoing transport staff competencies, education, and training;

(C) review and evaluate transports from initial activation of the transport team through delivery of patient, resources, quality of patient care provided, and patient outcomes; and

(D) integrate review findings into the overall neonatal QAPI Plan and process.

(3) The NMD may also serve as the TMD.

(e) NPM. The facility must identify an NPM who has the authority and oversight responsibilities written in his or her job description, for the provision of neonatal services through all phases of care, including discharge, and identifying variances in care for inclusion in the neonatal QAPI Plan.

(1) The NPM must be a registered nurse with defined education, credentials, and experience for neonatal care applicable to the level of care being provided.

(2) The NPM must maintain a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course.

(3) The NPM must:

(A) ensure staff competency in resuscitation techniques;

(B) participate in ongoing staff and team-based education and training in the care of the neonatal patient;

(C) monitor utilization of telehealth/telemedicine, if used;

(D) collaborate with the NMD, maternal program, consulting physicians, and nursing leaders and units providing neonatal care to include developing, implementing, or revising:

(i) written policies, procedures, and guidelines for neonatal care that are implemented and monitored for variances;

(ii) the neonatal QAPI Plan, specific reviews, and data initiatives;

(iii) criteria for transfer, consultation, or higher-level of care; and

(iv) staff competencies, education, and training;

(E) regularly and actively participate in neonatal care at the facility where program manager services are provided;

(F) consistently review the neonatal care provided and ensure the neonatal QAPI Plan is specific to neonatal/infant care, data driven, and outcome-based;

(G) frequently lead the meetings and participate in Neonatal Program Oversight and other neonatal meetings as appropriate; and

(H) develop and maintain collaborative relationships with other NPMs of designated neonatal facilities within the applicable PCR.

§133.186. Neonatal Designation Level I.

(a) Level I (Well Care). The Level I neonatal designated facility must:

(1) provide care for mothers and their infants of generally more than or equal to 35 weeks gestational age who have routine, transient perinatal problems;

(2) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served; and

(3) provide the same level of care that the neonate would receive at a higher-level designated neonatal facility and complete an in-depth critical review and assessment of the care provided to these infants through the neonatal QAPI Plan and process if an infant less than 35 weeks gestational age is retained.

(b) Neonatal Medical Director (NMD). The NMD must be a physician who:

(1) is a currently practicing pediatrician, family medicine physician, or physician specializing in obstetrics and gynecology with experience in the care of neonates/infants and with privileges in neonatal care;

(2) maintains a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course;

(3) demonstrates effective administrative skills and oversight of the neonatal QAPI Plan; and

(4) completes annual continuing medical education specific to the care of neonates.

(c) Program Functions and Services.

(1) The neonatal program must collaborate with the maternal program, consulting physicians, and nursing leadership to ensure pregnant mothers who are at high risk of delivering a neonate that requires a higher-level of care are transferred to a higher-level facility before delivery unless the transfer would be unsafe.

(2) The facility provides appropriate, supportive, and emergency care delivered by trained personnel for unanticipated maternal-fetal or neonatal problems that occur during labor and delivery through the disposition of the patient.

(3) The on-call physician, advanced practice nurse, or physician assistant must have documented special competence in the care of neonates, privileges and credentials to participate in neonatal/infant care reviewed by the NMD, and:

(A) must maintain a current status of successful completion of the NRP or a department-approved equivalent course;

(B) must complete annual continuing education specific to the care of neonates;

(C) must arrive at the patient bedside within 30 minutes of an urgent request;

(D) if not immediately available to respond or is covering more than one facility, must ensure appropriate back-up coverage is available, back-up call providers are documented in the neonatal on-call schedule and must be readily available to respond to the facility staff; and

(E) the back-up call physician, advanced practice nurse, or physician assistant must arrive at the patient bedside within 30 minutes of an urgent request.

(4) The facility must have written guidelines defining the availability of appropriate anesthesia, laboratory, radiology, respiratory, ultrasonography, and blood bank services on a 24-hour basis as described in §133.41 of this title (relating to Hospital Functions and Services).

(A) If preliminary reading of imaging studies pending formal interpretation is performed, the preliminary findings must be documented in the medical record.

(B) The facility must ensure regular monitoring and comparison of the preliminary and final readings through the radiology QAPI Plan. Summary reports of activities must be presented at the Neonatal Program Oversight.

(5) Pharmacy services must be in compliance with the requirements in §133.41 of this title and must have a pharmacist available at all times.

(A) If medication compounding is done by a pharmacy technician for neonates/infants, a pharmacist must provide immediate supervision of the compounding process.

(B) When medication compounding is done for neonates/infants, the pharmacist must implement guidelines to ensure the accuracy of the compounded final product and ensure:

(i) the process is monitored through the pharmacy QAPI Plan; and

(ii) summary reports of activities are presented to the Neonatal Program Oversight.

(6) The facility must have personnel with appropriate training for managing neonates/infants, written policies, procedures, and guidelines specific to the facility for the stabilization and resuscitation of neonates based on current standards of professional practice. The facility must ensure the availability of personnel who can stabilize distressed neonates, including those less than 35 weeks gestation until they are transferred to a higher-level facility. Variances from these standards are monitored through the neonatal QAPI Plan and process.

(A) Each birth must be attended by at least one person who maintains a current status of successful completion of the NRP or a department-equivalent course, whose primary focus is management of the neonate and initiating resuscitation.

(B) At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access, and administration of medications.

(C) Additional personnel with current status of successful completion of the NRP, or a department-equivalent course, must be on-site and immediately available upon request for the following:

(i) multiple birth deliveries, to care for each neonate;

(ii) deliveries with unanticipated maternal-fetal problems that occur during labor and delivery; and

(iii) deliveries determined or suspected to be high-risk for the pregnant patient or neonate.

(D) Variances from these standards are monitored through the neonatal QAPI Plan and process and reported at the Neonatal Program Oversight.

(E) Neonatal resuscitative equipment, supplies, and medications must be immediately available for trained personnel to perform resuscitation and stabilization on any neonate/infant.

(7) A registered nurse with experience in neonatal or perinatal care must provide supervision and coordination of staff education.

(8) The neonatal program ensures the availability of support personnel with knowledge and skills in breastfeeding and lactation to assist and counsel mothers.

(9) Social services, supportive spiritual care, and counseling must be provided as appropriate to meet the needs of the patient population served.

§133.187. Neonatal Designation Level II.

(a) Level II (Special Care). The Level II neonatal designated facility must:

(1) provide care for mothers and their infants of generally more than or equal to 32 weeks gestational age and birth weight more than or equal to 1500 grams who have physiologic immaturity or problems that are expected to resolve rapidly and are not anticipated to require subspecialty services on an urgent basis; and

(A) if a facility is located more than 75 miles from the nearest Level III or IV designated neonatal facility and retains a neonate less than 32 weeks of gestation or having a birth weight of less than 1500 grams, the facility must provide the same level of care that the neonate would receive at a higher-level designated neonatal facility; and

(B) any facility that retains a neonate less than 32 weeks of gestation or a birth weight less than 1500 grams, must, through the neonatal QAPI Plan, complete an in-depth critical review and assessment of the care provided;

(2) provide care, either by including assisted endotracheal ventilation for less than 24 hours or nasal continuous positive airway pressure (NCPAP) until the infant's condition improves or arrange for appropriate transfer to a higher-level designated facility; and

(A) if the facility performs neonatal surgery, it must provide the same level of care that the neonate would receive at a higher-level designated facility; and

(B) the neonatal surgical procedure and follow-up must be reviewed through the neonatal QAPI Plan; and

(3) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served.

(b) Neonatal Medical Director (NMD). The NMD must be a physician who:

(1) is a board-eligible/certified neonatologist, with experience in the care of neonates/infants and maintains a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course; or

(2) is a pediatrician or neonatologist by the effective date of this section who:

(A) continuously provided neonatal care for the last consecutive two years and has experience and training in the care of neonates/infants, including assisted endotracheal ventilation and NCPAP management;

(B) maintains a consultative relationship with a board-eligible/certified neonatologist;

(C) demonstrates effective administrative skills and oversight of the neonatal QAPI Plan;

(D) maintains a current status of successful completion of the NRP or a department-approved equivalent course; and

(E) must complete annual continuing medical education specific to the care of neonates.

(c) Program Functions and Services.

(1) The neonatal program must collaborate with the maternal program, consulting physicians, and nursing leadership to ensure pregnant patients who are at high risk of delivering a neonate that requires a higher-level of care are transferred to a higher-level facility before delivery unless the transfer would be unsafe.

(2) The facility provides appropriate, supportive, and emergency care delivered by trained personnel, for unanticipated maternal-fetal or neonatal problems that occur during labor and delivery through the disposition of the patient.

(3) The on-call physician, advanced practice nurse, or physician assistant must have documented special competence in the care of neonates, privileges and credentials to participate in neonatal/infant care reviewed by the NMD, and:

(A) must maintain a current status of successful completion of the NRP or a department-approved equivalent course;

(B) must complete annual continuing education specific to the care of neonates;

(C) must arrive at the patient bedside within 30 minutes of an urgent request;

(D) if not immediately available to respond or is covering more than one facility, must ensure appropriate back-up coverage is available, back-up call providers are documented in the neonatal on-call schedule and must be readily available to respond to the facility staff;

(i) the back-up call physician, advanced practice nurse, or physician assistant must arrive at the patient bedside within 30 minutes of an urgent request; and

(ii) the on-call staff must be on-site to provide ongoing care and to respond to emergencies when a neonate/infant is maintained on endotracheal ventilation.

(4) The neonatal program ensures if surgeries are performed for neonates/infants, a surgeon privileged and credentialed to perform surgery on a neonate/infant is on-call and must arrive at the patient bedside within a time period consistent with current standards of professional practice and neonatal care. Surgeon response times must be reviewed and monitored through the neonatal QAPI Plan.

(5) Anesthesia providers with pediatric experience and competence must provide services in compliance with the requirements in §133.41 of this title (relating to Hospital Functions and Services).

(6) Dietitian or nutritionist with appropriate training and experience in neonatal nutrition provides services for the population served in compliance with the requirements in §133.41 of this title.

(7) Laboratory services must be in compliance with the requirements in §133.41 of this title and must have:

(A) personnel on-site at all times as defined by written management guidelines, which may include when a neonate/infant is maintained on endotracheal ventilation; and

(B) a blood bank capable of providing blood and blood component therapy within the timelines defined in approved blood transfusion guidelines.

(8) The facility must provide neonatal/infant blood gas monitoring capabilities.

(9) Pharmacy services must be in compliance with the requirements in §133.41 of this title and must have a pharmacist with experience in neonatal/pediatric pharmacology available at all times.

(A) If medication compounding is done by a pharmacy technician for neonates/infants, a pharmacist must provide immediate supervision of the compounding process.

(B) When medication compounding is done for neonates/infants, the pharmacist must implement guidelines to ensure the accuracy of the compounded final product and ensure:

(i) the process is monitored through the pharmacy QAPI Plan; and

(ii) summary reports of activities are presented at the Neonatal Program Oversight.

(C) Total parenteral nutrition appropriate for neonates/infants must be available, if requested.

(10) A speech, occupational, or physical therapist with sufficient neonatal expertise must provide therapy services to meet the needs of the population served.

(11) Radiology services must be in compliance with the requirements in §133.41 of this title, incorporate the "As Low as Reasonably Achievable" principle when obtaining imaging in neonatal patients, and must have:

(A) personnel appropriately trained in the use of x-ray and ultrasound equipment;

(B) personnel at the bedside within 30 minutes of an urgent request;

(C) personnel appropriately trained, available on-site to provide ongoing care and to respond to emergencies when an infant is maintained on endotracheal ventilation;

(D) interpretation capability of neonatal and perinatal x-rays and ultrasound studies are available at all times;

(E) if preliminary reading of imaging studies pending formal interpretation is performed, the preliminary findings must be documented in the medical record; and

(F) regular monitoring and comparison of preliminary and final readings through the radiology QAPI Plan and provide summary reports of activities at the Neonatal Program Oversight.

(12) A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed by the NMD, must be immediately available on-site when:

(A) a neonate/infant is on a respiratory ventilator to provide ongoing care and to respond to emergencies; or

(B) a neonate/infant is on a Continuous Positive Airway Pressure (CPAP) apparatus.

(13) The facility must have staff with appropriate training for managing neonates/infants, written policies, procedures, and guidelines specific to the facility for the stabilization and resuscitation of neonates based on current standards of professional practice. Variances from these standards are monitored through the neonatal QAPI Plan.

(A) Each birth must be attended by at least one person who maintains a current status of successful completion of the NRP or a department-approved equivalent course, whose primary focus is management of the neonate and initiating resuscitation.

(B) At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access, and administration of medications.

(C) Additional personnel who maintain a current status of successful completion of the NRP or a department-approved equivalent course must be on-site and immediately available upon request for the following:

(i) multiple birth deliveries, to care for each neonate;

(ii) deliveries with unanticipated maternal-fetal problems that occur during labor and delivery; and

(iii) deliveries determined or suspected to be high-risk for the pregnant patient or neonate.

(D) Variances from these standards are monitored through the neonatal QAPI Plan and process and reported at the Neonatal Program Oversight.

(E) Neonatal resuscitative equipment, supplies, and medications must be immediately available for trained staff to perform resuscitation and stabilization on any neonate/infant.

(14) A registered nurse with experience in neonatal care, including special care, or perinatal care must provide supervision and coordination of staff education.

(15) Social services, supportive spiritual care, and counseling must be provided as appropriate to meet the needs of the patient population served.

(16) Written and implemented policies and procedures to ensure the timely evaluation of retinopathy of prematurity, documented referral for treatment, and follow-up of an at-risk infant, which must be monitored through the neonatal QAPI Plan.

(17) The neonatal program ensures the availability of support personnel with knowledge and expertise in breastfeeding and lactation to assist and counsel mothers.

(18) The neonatal program ensures provisions for follow-through care at discharge for infants at high risk for neurodevelopmental, medical, or psychosocial complications.

§133.188. Neonatal Designation Level III.

(a) Level III (Neonatal Intensive Care). The Level III neonatal designated facility must:

(1) provide care for mothers and comprehensive care for their infants of all gestational ages with mild to critical illnesses or requiring sustained life support;

(2) ensure access to consultation to a full range of pediatric medical subspecialists and pediatric surgical specialists, and the capability to perform major pediatric surgery on-site or at another appropriate neonatal designated facility;

(3) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served;

(4) facilitate neonatal transports; and

(5) provide outreach education related to trends identified through the neonatal QAPI Plan, specific requests, and system needs to lower-level neonatal designated facilities, and as appropriate and applicable, to non-designated facilities, birthing centers, independent midwife practices, and prehospital providers.

(b) Neonatal Medical Director (NMD). The NMD must be a physician who is a board-eligible/certified neonatologist with experience in the care of neonates/infants and maintains a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course.

(c) If the facility has its own transport program, there must be an identified Transport Medical Director (TMD). The TMD or Trans-

port Medical Co-Director must be a physician who is a board-eligible/certified neonatologist or pediatrician with expertise and experience in neonatal/infant transport.

(d) Program Functions and Services.

(1) The neonatal program must collaborate with the maternal program, consulting physicians, and nursing leadership to ensure pregnant patients who are at high risk of delivering a neonate that requires a higher-level of care are transferred to a higher-level facility before delivery unless the transfer would be unsafe.

(2) The facility provides appropriate, supportive, and emergency care delivered by trained personnel for unanticipated maternal-fetal or neonatal problems that occur during labor and delivery through the disposition of the patient.

(3) At least one of the following neonatal providers must be on-site and available at all times: pediatric hospitalists, neonatologists, neonatal nurse practitioners, or neonatal physician assistants, as appropriate, who must have documented competence in the management of severely ill neonates/infants, and privileges and credentials to participate in neonatal/infant care reviewed by the NMD and:

(A) must maintain a current status of successful completion of the NRP or a department-approved equivalent course;

(B) must complete annual continuing education specific to the care of neonates;

(C) must have a neonatologist available for consultation at all times that arrives on-site within 30 minutes of an urgent request, if the on-site provider is not a neonatologist; and

(D) if the neonatologist is covering more than one facility, must ensure the facility has a back-up neonatologist available, the back-up neonatologist is documented in the neonatal on-call schedule, and readily available to respond to the facility staff and arrive at the patient bedside within 30 minutes of an urgent request.

(4) The neonatal program that performs surgeries for neonates/infants must have a surgeon privileged and credentialed to perform surgery on a neonate/infant on-call. The surgeon on-call must be available to arrive at the patient bedside within a time period consistent with current standards of professional practice and neonatal care. Surgeon response times must be reviewed and monitored through the neonatal QAPI Plan.

(5) Anesthesiologists with pediatric expertise and competence must direct and evaluate anesthesia care provided to neonates in compliance with the requirements in §133.41 of this title.

(6) Dietitian or nutritionist with appropriate training and experience in neonatal nutrition, plans diets that meet the needs of the neonate/infant and provides services for the population served, in compliance with the requirements in §133.41 of this title.

(7) Laboratory services must be in compliance with the requirements in §133.41 of this title and must have:

(A) laboratory personnel on-site at all times;

(B) pediatric pathology services available for the population served;

(C) pediatric surgical or intra-operative frozen section pathology services available in the operative suite at the request of the operating surgeon; and

(D) a blood bank capable of providing blood and blood component therapy within the timelines defined in approved blood transfusion guidelines.

(8) The facility must provide neonatal/infant blood gas monitoring capabilities.

(9) Pharmacy services must be in compliance with the requirements in §133.41 of this title and must have a pharmacist with experience in neonatal/pediatric pharmacology available at all times.

(A) If medication compounding is done by a pharmacy technician for neonates/infants, a pharmacist must provide immediate supervision of the compounding process;

(B) When medication compounding is done for neonates/infants, the pharmacist must implement guidelines to ensure the accuracy of the compounded final product and ensure:

(i) the process is monitored through the pharmacy QAPI Plan; and

(ii) summary reports of activities are presented at the Neonatal Program Oversight.

(C) Total parenteral nutrition appropriate for neonates/infants must be available.

(10) Radiology services must be in compliance with the requirements in §133.41 of this title, incorporate the "As Low as Reasonably Achievable" principle when obtaining imaging in neonatal patients, and must have:

(A) personnel appropriately trained in the use of x-ray equipment on-site and available at all times;

(B) personnel appropriately trained in ultrasound, computed tomography, and cranial ultrasound equipment available on-site within a time period consistent with current standards of professional practice;

(C) fluoroscopy available at all times;

(D) neonatal diagnostic imaging studies and radiologists with pediatric expertise to interpret the neonatal diagnostic imaging studies, available at all times;

(E) a radiologist with pediatric expertise to interpret images consistent with the patient condition and within a time period consistent with current standards of professional practice with monitoring of variances through the neonatal QAPI Plan and process;

(F) preliminary findings documented in the medical record, if preliminary reading of imaging studies pending formal interpretation is performed; and

(G) regular monitoring and comparison of the preliminary and final readings through the radiology QAPI Plan and provide summary reports of activities at the Neonatal Program Oversight.

(11) Pediatric echocardiography with pediatric cardiology interpretation and consultation completed within a time period consistent with current standards of professional practice.

(12) Speech, occupational, or physical therapists with neonatal/infant expertise and experience must:

(A) evaluate and recommend management of feeding or swallowing disorders as appropriate for the patient's condition; and

(B) provide therapy services to meet the needs of the population served.

(13) A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed by the NMD, must be on-site and immediately available.

(14) The facility must have staff with appropriate training for managing neonates/infants and written policies, procedures, and guidelines specific to the facility for the stabilization and resuscitation of neonates based on current standards of professional practice. Variances from these standards are monitored through the neonatal QAPI Plan.

(A) Each birth must be attended by at least one person who maintains a current status of successful completion of the NRP or a department-approved equivalent course, and whose primary focus is management of the neonate and initiating resuscitation.

(B) At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access, and administration of medications.

(C) Additional personnel who maintain a current status of successful completion of the NRP or a department-approved equivalent course must be on-site and immediately available upon request for the following:

(i) multiple birth deliveries, to care for each neonate;

(ii) deliveries with unanticipated maternal-fetal problems that occur during labor and delivery; and

(iii) deliveries determined or suspected to be high-risk for the pregnant patient or neonate.

(D) Variances from these standards are monitored through the neonatal QAPI Plan and process and reported at the Neonatal Program Oversight.

(E) Neonatal resuscitative equipment, supplies, and medications must be immediately available for trained staff to perform complete resuscitation and stabilization for each neonate/infant.

(15) A registered nurse with experience in neonatal care, including neonatal intensive care, must provide supervision and coordination of staff education.

(16) Social services, supportive spiritual care, and counseling must be provided as appropriate to meet the needs of the patient population served.

(17) Written and implemented policies and procedures to ensure timely evaluation of retinopathy of prematurity, documented referral for treatment and follow-up of an at-risk infant, which must be monitored through the neonatal QAPI Plan.

(18) The neonatal program ensures a certified lactation consultant must be available at all times to assist and counsel mothers.

(19) The neonatal program ensures provisions for follow-through care at discharge for infants at high risk for neurodevelopmental, medical, or psychosocial complications.

§133.189. Neonatal Designation Level IV.

(a) Level IV (Advanced Neonatal Intensive Care). The Level IV neonatal designated facility must:

(1) provide care for the mothers and comprehensive care for their infants of all gestational ages with the most complex and critical medical and surgical conditions or requiring sustained life support;

(2) ensure access to a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists are available to arrive on-site in person for consultation and care, and the capability to perform major pediatric surgery including the surgical repair of complex conditions on-site;

(3) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served;

(4) facilitate neonatal transports; and

(5) provide outreach education related to trends identified through the neonatal QAPI Plan, specific requests, and system needs to lower-level neonatal designated facilities, and as appropriate and applicable, to non-designated facilities, birthing centers, independent midwife practices, and prehospital providers.

(b) Neonatal Medical Director (NMD). The NMD must be a physician who is a board-eligible/certified neonatologist and maintains a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course.

(c) If the facility has its own transport program, there must be an identified Transport Medical Director (TMD). The TMD or Transport Medical Co-Director must be a physician who is a board-eligible/certified neonatologist with expertise and experience in neonatal/infant transport.

(d) Program Functions and Services.

(1) The neonatal program must collaborate with the maternal program, consulting physicians, and nursing leadership to ensure pregnant patients who are at high risk of delivering a neonate that requires specialized care are transferred to a facility with specialized care capabilities before delivery unless the transfer would be unsafe.

(2) The facility provides appropriate, supportive, and emergency care delivered by trained personnel for unanticipated maternal-fetal or neonatal problems that occur during labor and delivery, through the disposition of the patient.

(3) A board-eligible/certified neonatologist, with documented competence in the management of the most complex and critically ill neonates/infants, with neonatal privileges and credentials reviewed by the NMD, must be on-site and immediately available at the neonate/infant bedside as requested. The neonatologist:

(A) must maintain a current status of successful completion of the NRP or a department-approved equivalent course;

(B) must complete annual continuing education specific to the care of neonates; and

(C) must ensure the facility has a back-up neonatal provider if the neonatologist is not immediately available.

(4) Pediatric anesthesiologists must direct and evaluate anesthesia care provided to neonates in compliance with the requirements in §133.41 of this title (relating to Hospital Functions and Services).

(5) A comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists privileged and credentialed to participate in neonatal/infant care must be available to arrive on-site for in-person consultation and care within a time period consistent with current standards of professional practice and neonatal care. The pediatric medical and pediatric surgical subspecialists' response times must be reviewed and monitored through the neonatal QAPI Plan.

(6) Dietitian or nutritionist with appropriate training and experience in neonatal nutrition, plans diets that meet the needs of the neonate/infant and critically ill neonatal patient and provides services for the population served, in compliance with the requirements in §133.41 of this title.

(7) Laboratory services must be in compliance with the requirements in §133.41 of this title and must have:

(A) appropriately trained and qualified laboratory personnel on-site at all times;

(B) pediatric pathology services available for the population served;

(C) pediatric surgical or intra-operative frozen section pathology services available in the operative suite at the request of the operating surgeon; and

(D) a blood bank capable of providing blood and blood component therapy within the timelines defined in approved blood transfusion guidelines.

(8) The facility must provide neonatal/infant blood gas monitoring capabilities.

(9) Pharmacy services must be in compliance with the requirements in §133.41 of this title and must have a pharmacist with experience in neonatal/pediatric pharmacology available on-site at all times.

(A) If medication compounding is done by a pharmacy technician for neonates/infants, a pharmacist must provide immediate supervision of the compounding process.

(B) When medication compounding is done for neonates/infants, the pharmacist must implement guidelines to ensure the accuracy of the compounded final product and must ensure:

(i) the process is monitored through the pharmacy QAPI plan; and

(ii) summary reports of activities are presented at the Neonatal Program Oversight.

(C) Total parenteral nutrition appropriate for neonates/infants must be available.

(10) Radiology services must be in compliance with the requirements in §133.41 of this title, incorporate the "As Low as Reasonably Achievable" principle when obtaining imaging in neonatal patients, and must have:

(A) personnel appropriately trained in the use of x-ray equipment on-site and available at all times;

(B) personnel appropriately trained in ultrasound, computed tomography, and cranial ultrasound equipment be on-site within a time period consistent with current standards of professional practice;

(C) fluoroscopy be available at all times;

(D) neonatal diagnostic imaging studies and radiologists with pediatric expertise to interpret neonatal diagnostic imaging studies, available at all times;

(E) a radiologist with pediatric expertise to interpret images consistent with the patient condition and within a time period consistent with current standards of professional practice with monitoring of variances through the neonatal QAPI Plan and process;

(F) preliminary findings documented in the medical record, if preliminary reading of imaging studies pending formal interpretation is performed; and

(G) regular monitoring and comparison of the preliminary and final readings through the radiology QAPI Plan and provide a summary report of activities at the Neonatal Program Oversight.

(11) Pediatric echocardiography with pediatric cardiology interpretation and consultation completed within a time period consistent with current standards of professional practice.

(12) Speech, occupational, or physical therapists with neonatal/infant expertise and experience must:

(A) evaluate and recommend management of feeding and swallowing disorders as appropriate for the patient's condition; and

(B) provide therapy services to meet the needs of the population served.

(13) A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed and approved by the Neonatal Medical Director, must be on-site and immediately available.

(14) The facility must have staff with appropriate training for managing neonates/infants, written policies, procedures, and guidelines specific to the facility for the stabilization and resuscitation of neonates/infants based on current standards of professional practice. Variances from these standards are monitored through the neonatal QAPI Plan.

(A) Each birth must be attended by at least one person who maintains a current status of successful completion of the NRP or a department-approved equivalent course and whose primary focus is management of the neonate and initiating resuscitation.

(B) At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access and administration of medications.

(C) Additional personnel who maintain a current status of successful completion of the NRP or a department-approved equivalent course must be on-site and immediately available upon request for the following:

(i) multiple birth deliveries, to care for each neonate;

(ii) deliveries with unanticipated maternal-fetal problems that occur during labor and delivery; and

(iii) deliveries determined or suspected to be high-risk for the pregnant patient or neonate.

(D) Variances from these standards are monitored through the neonatal QAPI Plan and process and reported at the Neonatal Program Oversight.

(E) Neonatal resuscitative equipment, supplies, and medications must be immediately available for trained staff to perform complete resuscitation and stabilization for each neonate/infant.

(15) A registered nurse with experience in neonatal care, including advanced neonatal intensive care, must provide supervision and coordination of staff education.

(16) Social services, supportive spiritual care, and counseling must be provided as appropriate to meet the needs of the patient population served.

(17) Written and implemented policies and procedures to ensure timely evaluation and treatment of retinopathy of prematurity on-site by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity of an at-risk infant. Patient follow-up of retinopathy of prematurity must be documented and monitored through the neonatal QAPI Plan.

(18) The neonatal program ensures a certified lactation consultant must be available at all times to assist and counsel mothers.

(19) The neonatal program ensures provisions for follow-through care at discharge for infants at high risk for neurodevelopmental, medical, or psychosocial complications.

§133.190. Survey Team.

(a) The survey team composition must be as follows:

(1) Level I facilities neonatal program staff must conduct a self-survey, documenting the findings on the approved department survey form. The department may periodically require validation of the survey findings by an on-site review conducted by department staff.

(2) Level II facilities must be surveyed by a multidisciplinary team that includes, at a minimum, one neonatologist and one neonatal nurse who:

(A) have completed a department survey training course;

(B) have observed a minimum of one neonatal survey;

(C) are currently active in the management of neonatal patients and active in the neonatal QAPI Plan and process at a facility providing the same or a higher-level of neonatal care; and

(D) meet the criteria outlined in the department survey guidelines.

(3) Level III facilities must be surveyed by a multidisciplinary team that includes, at a minimum, one neonatologist, one neonatal nurse, and a pediatric surgeon when neonatal surgery is performed in the facility, who:

(A) have completed a survey training course;

(B) have observed a minimum of one neonatal survey;

(C) are currently active in the management of neonatal patients and active in the neonatal QAPI Plan and process at a facility providing the same or a higher-level of neonatal care; and

(D) meet the criteria outlined in the department survey guidelines.

(4) Level IV facilities must be surveyed by a multidisciplinary team that includes, at a minimum, one neonatologist, one neonatal nurse, and one pediatric surgeon, who:

(A) have completed a survey training course;

(B) have observed a minimum of one neonatal survey;

(C) are currently active in the management of neonatal patients and active in the neonatal QAPI Plan and process at a facility providing the same level of neonatal care; and

(D) meet the criteria outlined in the department survey guidelines.

(b) All members of the survey team, except department staff, must come from a PCR outside the facility's region or a contiguous region.

(c) Survey team members cannot have a conflict of interest:

(1) A conflict of interest exists when a surveyor has a direct or indirect financial, personal, or other interest which would limit or could reasonably be perceived as limiting the surveyor's ability to serve in the best interest of the public. The conflict of interest may include a surveyor who, within the past four years, has personally trained a key member of the facility's leadership in residency or fellowship, collaborated with a key member of the facility's leadership professionally, participated in a designation consultation with the facility, or conducted a designation survey for the facility.

(2) If a designation survey occurs with a surveyor who has a conflict of interest, the department, in its sole discretion, may refuse to accept the neonatal designation site survey summary conducted by a surveyor with a conflict of interest.

(d) The survey team must follow the department survey guidelines to evaluate and validate that the facility demonstrates the designation requirements are met.

(e) The survey team must evaluate appropriate use of telehealth/telemedicine utilization for neonatal care.

(f) All information and materials submitted by a facility to the department and a survey organization under Texas Health and Safety Code, §241.183(d) or this subchapter, are subject to confidentiality as articulated in Texas Health and Safety Code, §241.184, Confidentiality; Privilege, and are not subject to disclosure under Texas Government Code, Chapter 552, or discovery, subpoena, or other means of legal compulsion for release to any person.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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TITLE 26. HEALTH AND HUMAN SERVICES

PART 1. HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 565. HOME AND COMMUNITY-BASED (HCS) PROGRAM AND COMMUNITY FIRST CHOICE (CFC) CERTIFICATION STANDARDS

The Executive Commissioner of Health and Human Services Commission (HHSC) adopts in Texas Administrative Code (TAC) Title 26, Part 1, Chapter 565, Home and Community-based Program (HCS) Certification Standards, new §§565.2, 565.3, 565.5, 565.7, 565.9, 565.11, 565.13, 565.15, 565.17, 565.19, 565.21, 565.23, 565.25, 565.27, 565.29, 565.31, 565.33, 565.35, 565.37, 565.39, 565.41, 565.43, 565.47, and 565.49.

New §§565.3, 565.5, 565.9, 565.11, 565.13, 565.15, 565.17, 565.19, 565.21, 565.23, 565.25, 565.27, 565.31, 565.35, 565.37, and 565.49 are adopted with changes to the proposed text as published in the February 17, 2023, issue of the *Texas Register* (48 TexReg 789). These rules will be republished. These rules contain references to §565.45, Administrative Penalties, which is being administratively transferred from 40 TAC §9.181, effective the same day these rules are adopted.

New §§565.2, 565.7, 565.29, 565.33, 565.39, 565.41, 565.43, and 565.47 are adopted without changes to the proposed text as published in the February 17, 2023, issue of the *Texas Register* (48 TexReg 789). These rules will not be republished.

BACKGROUND AND JUSTIFICATION